

AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions and listings of claims in the application:

Listing of claims

1. (Currently Amended) A method for increasing therapeutic gain in chemotherapy or radiotherapy, comprising

administering a composition containing a histone hyperacetylating agent and a pharmaceutically acceptable carrier or a pharmaceutically acceptable salt thereof to a subject undergoing chemotherapy or radiotherapy in need, and

evaluating the subject for a therapeutic effect of the composition on the skin, mucosa, injured normal tissue, or epithelium of the subject,

wherein (A) the therapeutic gain in chemotherapy is: (i) simultaneously

(1) enhancing the suppression of tumor or proliferating cell growth in the subject a host in need of radiotherapy and/or chemotherapy, and

(2) sensitizing tumors to chemotherapy,

(3) ameliorating complications or sequelae of a disorder, both of which are induced by radiation or chemotherapy, wherein the disorder is being selected from the group consisting of mucositis, dermatitis, ulceration, tissue necrosis, fibrosis, xerostomia, and plantar-palmar syndrome; and

(ii) protecting normal tissues from cell death induced by chemotherapy; or (iii) promoting radiation-induced wound healing in mucositis and dermatitis and

(B) the therapeutic gain in radiotherapy is:

(1) downregulating inflammatory cytokines or reducing inflammatory cell infiltration,

(2) reducing or preventing radiation-induced tissue damage, the damage being selected from the group consisting of desquamation, dermatitis, mucositis, epidermal atrophy, fibrosis, ulceration, tissue necrosis, and bulla formation,

(3) increasing epithelium thickness, reducing dermis thickness, or reducing vessel density.

(4) decreasing collagen deposition,
(5) enhancing tumor radiosensitization, or
(6) downregulating fibrogenic growth factors or preventing late radiation-induced tumorogenesis.

2. (Currently Amended and Withdrawn) The method as claimed in claim 1, wherein the method is for increasing increased therapeutic gain is in chemotherapy and the therapeutic gain in chemotherapy is simultaneously enhancing tumor radiosensitization or sensitizing tumors to chemotherapy, increasing tumor growth inhibition, promoting wound healing in mucositis and dermatitis, preventing/reducing severity of plantar-palmar syndrome, decreasing tissue fibrosis, protecting normal tissue from cell death, preventing xerostomia, and suppressing tumorogenesis.

3. (Withdrawn) The method as claimed in claim 1, wherein the hyperacetylating agent is a histone deacetylase inhibitor.

4. (Original) The method as claimed in claim 1, wherein the radiotherapy is teletherapy, brachytherapy, or ionizing radiation.

5-6. (Cancelled)

7. (Withdrawn) The method as claimed in claim 1, wherein the histone hyperacetylating agent is trichostatin A, or trichostatin C.

8. (Withdrawn) The method as claimed in claim 1, wherein the histone hyperacetylating agent is selected from a group consisting of oxamflatin, trapoxin A, FR901228, apicidin, HC-Toxin, WF27082, and chlamydocin.

9. (Withdrawn) The method as claimed in claim 1, wherein the histone hyperacetylating agent is selected from a group consisting of salicylihydroxamic acid, suberoylanilide hydroxamic acid, and azelaic bishydroxamic acid.

10. (Withdrawn) The method as claimed in claim 1, wherein the histone hyperacetylating agent is selected from a group consisting of azelaic-1-hydroxamate-9-an-ilide, M-carboxycinnamic acid bishydroxamide, 6-(3-chlorophenylureido)carp-oic hydroxamic acid, MW2796, and MW2996.

11 (Previously Presented) The method as claimed in claim 1, wherein the histone hyperacetylating agent is selected from the group consisting of sodium butyrate, isovalerate, valerate, 4-phenylbutyrate, Sodium phenylbutyrate, propionate, butryamide, isobutyramide, phenylacetate, 3-bromopropionate, valproic Acid, and tributyrin.

12. (Withdrawn) The method as claimed in claim 1, wherein the histone hyperacetylating agent is MS-27-275 or the 3'-amino derivatives thereof.

13. (Withdrawn) The method as claimed in claim 1, wherein the histone hyperacetylating agent is depudecin or scriptaid.

14. (Original) The method as claimed in claim 1, wherein the administrating is non-oral.

15. (Original) The method as claimed in claim 1, wherein the composition is a cream, an ointment, a gel, a paste, a powder, a lotion, a patch, a suppository, a liposome formation, a suspension, a mouth wash, an enema, an injection solution, or a drip infusion.

16. (Original) The method as claimed in claim 1, wherein the hyperacetylating agent is from 0.001% to 100% by weight of the composition.

17 (Original) The method as claimed in claim 1, wherein the composition further comprises a second agent selected from a group consisting of a cytokine, an interleukin, an anti-cancer agent or an anti-neoplastic agent, an anti-angiogenesis agent, a chemotherapeutic agent, an antibody, a conjugated antibody, an immune stimulant, an antibiotic, retinoic acid, a tyrosine kinase inhibitor, a hormone antagonist, and a growth stimulant.

18. (Withdrawn) The method as claimed in claim 17, wherein the conjugated antibody is selected from a group consisting of Trastuzumab, c225, Rituximab, and Cetuximab.

19. (Withdrawn) The method as claimed in claim 17, wherein the chemotherapeutic agent is selected from a group consisting of an alkylating agent, a purine analog, a pyrimidine analog, a vinca alkaloid, a vinca-like alkaloid, etoposide, an etoposide-like drug, a corticosteroid, a nitrosourea, an antimetabolite, a platinum-based cytotoxic drug, an anti-androgen, and an anti-estrogen.

20. (Withdrawn) The method as claimed in claim 17, wherein the anti-angiogenesis agent is selected from a group consisting of thalidomide, SU5416, SU6668, Thrombospondin-1, endostatin, and angiostatin.

21. (Withdrawn) The method as claimed in claim 17, wherein the antibiotic is Ganciclovir, Acyclovir, or Famciclovir.

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22. (New) The method as claimed in claim 1, wherein the method is for increasing therapeutic gain in radiotherapy and the therapeutic gain in radiotherapy is (1), (2), (3), or (4).

23. (New) The method as claimed in claim 1, wherein the method is for increasing therapeutic gain in radiotherapy and the therapeutic gain in radiotherapy is (5) or (6).